User's Manual

FL-X
Humidifier

CE 0123

This appliance conforms with the Directive 93/42/CEE "Medical Devices".

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GMBH.

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Thank you for choosing a Spencer product

1 GENERAL INFORMATION

1.1 AIM AND CONTENTS

The aim of this manual is to supply all the information necessary so that the client, will not only attain adequate use of the appliance, he will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 CONSERVATION OF THE INSTRUCTION MANUAL

The instruction and maintenance manual must be kept with the product, inside the specially provided container and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 SYMBOLS USED

SYMBOL	MEANING
	General or specific warning
	See instructions for use
	Lot number
	Product code
	The product is compliant with the specifications of the Directive 93/42/CEE

1.4 SERVICING REQUESTS

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on 0039 0521 541111 - fax 0039 0521 541222 - e-mail: info@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY.

1.5 DEMOLITION

Follow the current regulations. When use has terminated, any liquid remaining should be removed and appropriately disposed of in specialized areas.

1.6 LABELLING

The serial number as indicated below can be found on each appliance and must not be removed or covered. In order to facilitate assistance please indicate or communicate the lot number (LOT) on the label.

2 WARNINGS

2.1 GENERAL WARNINGS

- Before carrying out any kind of operation on the appliance, the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l., for any necessary clarifications.
- Regularly check the appliance. Carry out the prescribed maintenance in order to keep the appliance in good condition and to guarantee correct functioning and a long life.
- In the case of any abnormalities or damage to the appliance, which could jeopardize the functioning and the safety, the appliance must be immediately removed from service.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with. In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself. Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Handle with care.

2.2 SPECIFIC WARNINGS

- This product should be used exclusively by properly trained specialised staff.
- Failure to follow these instructions can cause serious harm to people and/or objects.
- The device is not to be used on newborns.
- This device must not be used with lung ventilators.
- The humidifier FL-X is designed for use on patients who have not had their epiglottis airways by passed.
- The device must not be used for patients that have undergone tracheotomy and with assisted lung ventilation systems.
- The FL-X humidifier must be filled with sterile demineralised water.
- The device should be kept in the vertical position during use in order to guarantee the correct functioning of the humidifier.
- Follow the temperature and humidity ranges given for use and for storage so as to guarantee the correct functioning of the device.
- The flow meters, the tubes and other accessories used for connection of the FL-X humidifier for oxygen therapy should be adapt to the therapy in use and compatible with this humidifier.
- Failure to use original accessories and spare parts which may not be conform to the current requirements for the special technical functions, can compromise the functioning and safety of the device and consequently be a danger to both user and patient.
- The humidifier must not be dismounted when under pressure.
- No parts of the humidifier require lubricating.
- Take care in handling the device during transport and maintain clean and disinfected.

2.3 CONTRAINDICATIONS AND SIDE EFFECTS

The use of this device, if used as described in this manual, does not present any contra-indications or collateral effects.

3 DESCRIPTION OF PRODUCT

3.1 INTENDED USE

FL-X humidifier is a devices which permits the increase in the level of humidity of the oxygen being administrated to the patient during oxygen therapy. This is necessary as normally oxygen for medical use does not have the correct grade of humidity for it to be physiologically tolerated.
The device has to be used with two other medical devices: the flowmeter, which regulates the flow of oxygen supplied, and the mask or nasal cannula for the oxygen inhalation by the patient.

The device is not to be used with newborns and it must not be used with lung ventilators.

3.2 MAIN COMPONENTS

The main components of the FL-X humidifier are:

- Vase
- Lid
- Tube connector for administration of oxygen to patient
- Diffuser

3.3 MODELS

FL08302B FL-X Humidifier
FL08309B FL-X Humidifier with 1/4 " G connection
FL08310B FL-X Humidifier with 9/16 UNF connection

3.4 TECHNICAL DATA

Height	140 mm
Width	70 mm
Weight	160 g
Maximum volume	130 ml
Inlet connection	M 8
Outlet tube connector	Ø 7 mm
Pressure in use	350 kPa / 3,5 bar
Maximum pressure in use	500 kPa / 5 bar
Maximum supply flow	20 L/min
Material	Polycarbonate and carbon steel

3.5 ENVIRONMENTAL CONDITIONS

Functioning temperature: from +5 to +40 °C
Storage temperature: from 0 to +40 °C
Relative humidity: from 0 to 85 %
Operating gas inlet temperature range: from +5 to +40 °C

4 OPERATING INSTRUCTIONS

4.1 TRANSPORT AND STORAGE

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks, bumps or falls during the transport itself. Keep the original packaging for use in case of any further transport. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. The appliance must be stored in a dry place free from humidity.

4.2 PREPARATION

When opening the package, check the integrity of the humidifier and that there is no visible damage to any of the components. Remove the humidifier from its protective packaging. Unscrew the transparent jar from the white lid. Connect the humidifier to the flowmeter with a source at 3,5 bar (350 kPa) 0-15 L/min and with the help of a size 15 key the aerosol to the flowmeter or to a flow selector 3,5 bar 0-15 L/min exit using a suitable connector (1/4 " G o 9/16 UNF).

The temperature of the liquid used to fill the jar of the humidifier must not exceed 37 °C.

Manually screw up using about 10 Nm so to be sure that the attachment is airtight holding the lid in one hand and screwing on the vase with the other. Connect the inlet to the exit of the flowmeter and apply the tube of the mask or the oxygen cannula (making sure they are the correct size for the patient being treated) to the outlet of the humidifier and turn the connection so that the tube is in the direction of the patient's mask. Check the presence of the O rings for the source connector and the vase; if they are not present it could cause a loss of oxygen towards the outside and consequently errors in the quantity of oxygen subministrated to the patient.
Adjust the flowmeter and the flow rate according to the therapy that the patient is being subjected to and using a sample flowmeter check that the value remains the same at the exit of the humidifier. After this check the humidifier is ready for us and the medical oxygen which passes through the device will be correctly humidified for the patient. The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage.

4.3 FUNCTIONING

The FL-X humidifier permits an increase in the relative humidity of the oxygen administered to the respiratory airways of the patient. In fact the gas supplied by the flowmeter, on passing through the demineralised sterile water contained inside the humidifier jar, collects sufficient humidity to make it physiologically tolerated by the patient undergoing oxygen therapy. The device has graded measurements printed on the jar which permit monitoring and filling to the correct level with sterile demineralised water used to humidify the oxygen. **The device should be kept in the vertical position during use in order to guarantee the correct functioning of the humidifier and the correct reading of the graduated scale on the flowmeter.**

To begin using the humidifier, follow these instructions:

- Regulate the flowmeter and the flow as required by the therapy that the patient is undergoing. The correct functioning of the humidifier can be confirmed by the presence of bubbling in the water inside the jar.
- Follow the prescribed medical therapy.
- Do not obstruct the tube as the pressure of the gas source could cause the outburst of the adjustable connector of the coupler on the cylinder and therefore be a cause of danger to both patient and operator.
- When the therapy has terminated, reduce the level indicated on the flowmeter to zero. After a few seconds the bubbling in the water in the humidifier will terminate.
- Remove the device from the flowmeter by unscrewing the threaded ring and detach the tube of the mask from the connector.
- Proceed to eliminate the remaining liquid following the procedures given in the paragraph 1.5 "Demolition".

During use, it is essential that the level of the liquid remains between the minimum and maximum level indicated on the jar. Before repeating use of the device, it must undergo the correct cleaning and sterilizing programme as indicated in the paragraph 5 "Maintenance and Cleaning".

4.4 TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
Leakage	The seals are worn out or insufficient	Immediately remove the device from service and contact the assistance centre
Poor performance	Life span, exceeded worn out	Check the product in an authorised assistance centre and if necessary substitute the device
Strange noises	Possible damage to components	Immediately remove the device from service and contact the manufacturer for substitution
Unstable outlet pressure	Obstructions, worn out parts, incorrect functioning of the pressure reducer	Immediately remove the device from service and contact the manufacturer for substitution

5 MAINTENANCE AND CLEANING

5.1 CLEANING

Cleaning and disinfecting should be carried out by qualified personnel.
Do not use solvents or abrasive products which could damage the surface of the device.
Do not use inflammable products or solvents and do not immerge the device in disinfectant. After each use the cleaning and sterilizing programme must be carried out as described:

- Dismantle the components of the humidifier: the lid, the connector, the diffuser and the jar.
- Wash the surface of the device accurately with hot water (temperature must not exceed 50 °C).
- Accurately dry the components using a soft cotton cloth.
- Put the parts in the autoclave taking care to put the jar upside and the lid in the position it is in for use. Complete the sterilizing programme with vapour at 120 °C for a maximum of 10 minutes (relative pressure 1 bar). The materials of the device are guaranteed for approx. 100 sterilizing cycles.
- Once the cycle has terminated and the components have cooled to room temperature, check that the parts are in good condition and show no damage and if necessary substitute with original spare parts.
- Reassemble the humidifier by inverting the instructions given for dismantling.

5.2 MAINTENANCE

5.2.1 Precautionary Maintenance

The person who carries out the precautionary maintenance of the appliance (user in person, manufacturer/supplier or a third party) has to guarantee the following basic requirements:

- Technical knowledge of the appliance and of the periodic maintenance procedures as described in these instructions.
- Specific qualifications and training in the maintenance operations of the appliance in question.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the manufacturer to maintain post sales records and traceability of the appliance if requested.

5.2.1.1 Six month check up routine

Functional check

Check the functioning as described in the paragraph 4.3 "Functioning".

Leakage check

In order to check for leakage the following instruments must be available:

- high pressure oxygen gas cylinder or equivalent source
- precision pressure reducer with zero to 1 atm grading
- high precision flowmeter with zero to 15-20 L/min grading

Connect humidifier to flowmeter. Connect the pressure reducer to the cylinder and attach 0,5 m of tube to the outlet. To the outlet of the flowmeter, connect another 0,5 m tube and to the other end of the tube connect the humidifier that has to be checked making sure that the outlet is air tight. Put the circuit under pressure regulating the reducer to 0,8 atm. Under these conditions the flowmeter should not indicate flow in excess of 10 L/min.

If the loss is higher than this, the damaged parts (for example the seals/O rings, the lid or the jar) must be substituted.

The person responsible for every day maintenance can only substitute the spare parts indicated on paragraph 6.2 "Spare Parts". All other substitutions or repairs can be carried out only by the manufacturer or by a centre authorised by the manufacturer.

5.2.2 Special servicing

Only the manufacturer or centres with written authorisation are authorised to complete any special servicing operations.

The device, if used as indicated in the following instruction manual, has an average life span of 2 years.

6 ACCESSORIES AND SPARE PARTS

6.1 ACCESSORIES

FL08303B	FL-X Flowmeter
PR00308B	Pressure regulator with dispenser
OX20139A	Oxymask 50 Medium concentration mask adult, box 10 pcs
OX20133A	Oxymask 50 Medium concentration mask paediatric, box 10 pcs
OX20132A	Oxymask 100 Variable concentration mask adult, box 10 pcs
OX20136A	Oxymask 100 Variable concentration mask paediatric, box 10 pcs
OX20134A	Oxymask 150 High concentration mask adult, box 10 pcs
OX20137A	Oxymask 150 High concentration mask paediatric, box 10 pcs
OX20138A	OXX 10 Tube for oxygen therapy, box 10 pcs
OX20131A	OXX 30 Anti-crush tube for oxygen therapy, box 10 pcs

6.2 SPARE PARTS

FL08307B	Lid with aerosol, tube connector and adaptor
FL08308B	Jar for humidifier

Warning

The information contained in this document can be modified without warning and is not to be intended as a commitment on the part of Spencer Italia S.r.l. Spencer products are exported to many countries in which the same identical regulations do not exist. It is for this reason that there can be many differences between the description and the actual product delivered. Spencer works continuously to reach the perfection of all the models sold. We therefore hope to have your understanding if we reserve the right to modify the shape, equipping, lay-out or technical aspects that are herein described, at any given time.

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